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6 Attorneys for Plaintiff  
Nutrishare, Inc.

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF CALIFORNIA

11 Nutrishop, Inc., a California corporation,  
12 Plaintiff,  
13 v.  
14 BioRx, LLC, an Ohio Limited Liability  
15 Company, Defendant

Case No. 2:08-CV-01252-WBS-EFB

**DECLARATION OF APARNA  
RAJAGOPAL DURBIN IN SUPPORT OF  
OPPOSITION TO DEFENDANT'S  
MOTION TO DISMISS OR TRANSFER**

Date: August 11, 2008  
Time: 2:00 p.m.  
Dept: Courtroom 5  
Judge: Hon. William B. Schubb

18 I, Aparna Rajagopal-Durbin, declare as follows:

19       1. I am an attorney licensed to practice law in the State of California and am counsel  
20 at Downey Brand LLP, attorneys of record for Nutrishare, Inc. (hereinafter “Nutrishare”) in this  
21 action. I have personal knowledge of the facts set forth herein, except to the extent they are stated  
22 on information and belief, and, if called to testify, I could and would testify competently to the  
23 contents hereof

24        2. Based on a search on [www.google.com](http://www.google.com), I learned that BioRx was an exhibitor in  
25 the 2005 annual meeting of the American Association of Neuromuscular and ElectroDiagnostic  
26 Medicine, which was held in Monterey, California. A true and correct copy of the list of  
27 exhibitors at this conference, available at

28 <http://www.aanem.org/industry/exhibit/exhibitorlisting.cfm>, is attached hereto as Exhibit A.

1 Based on the same Google search, I learned that on the same day as the Oley Conference this year  
2 – June 26 – BioRx was in attendance and marketing its products and services at the Neuropathy  
3 Action Foundation’s “Neuropathy Action Awareness Day” at the University of California San  
4 Francisco’s Mission Bay Conference Center. A true and correct copy of the list of exhibitors at  
5 this conference, available at

6 [http://www.neuropathyaction.org/patient\\_resources\\_news/neuropathy\\_action\\_awareness\\_day\\_2008.htm](http://www.neuropathyaction.org/patient_resources_news/neuropathy_action_awareness_day_2008.htm), is attached hereto as Exhibit B.

7       3. Also based on a Google search, I learned that BioRx worked with Bayer  
8 Healthcare, based in Berkeley, California, to publish a children’s book on hemophilia entitled  
9 “The Great Inhibitor,” in July, 2006. True and correct copies of press releases announcing this  
10 joint venture, available at

11 [http://www.kogenatefs.com/web\\_docs/09426Y%20The%20Great%20Inhibinato%20Press%20Release%20FINAL%207-18-06.pdf](http://www.kogenatefs.com/web_docs/09426Y%20The%20Great%20Inhibinato%20Press%20Release%20FINAL%207-18-06.pdf) and

12 [http://pharma.bayer.com/scripts/pages/en/news\\_room/archive/newsroom\\_archive20.php](http://pharma.bayer.com/scripts/pages/en/news_room/archive/newsroom_archive20.php), are  
13 attached hereto as Exhibit C.

14       4. Also based on a Google search, I learned that in 2006, BioRx had a Director of  
15 Business Development for the “West,” Julie Winston. True and correct copies of excerpts from  
16 the presentation made by Julie Winston at the 2006 Infusion Nurses Society Annual Meeting,  
17 available at <http://www.cealliance.org/IGIV%20Therapy.pdf>, are attached hereto as Exhibit D.

18       5. Our client was able to identify at least one family within this judicial district that  
19 uses NutriThrive products and services on the on-line forum [www.parent-2-parent.com](http://www.parent-2-parent.com). I logged  
20 on to this forum to find more information about this family, but unfortunately, was unable to view  
21 the family’s on-line profile because I did not have the requisite permissions. I was, however, able  
22 to determine that the poster’s name is Jessi, she is mother to Jaxson and Joshua, she lives in  
23 Redding, she posts under the user name “momtojaxandboo,” she has posted on the forum since at  
24 least February, 2008, she has posted hundreds of message to the forum since mid-April (previous  
25 messages are not available), and she appears to post several messages every day.

26       6. This afternoon, my colleague Michael Thomas and I spoke with Kristy Schieldge,

1 an attorney with the California Department of Consumer Affairs. Ms. Schieldge called us in  
2 response to a Public Records Act request that we delivered to the California Board of Pharmacy  
3 on July 17, 2008, in which we sought "Documents, correspondence, license applications, licenses,  
4 notes, and other Documents related to BioRx, LLC or NutriThrive, including but not limited to  
5 any Documents related to any applications for License No. 99504 (non-resident sterile  
6 compounding), and License No. 819 (non-resident pharmacy) or any other licenses or license  
7 applications." Ms. Schieldge notified us that she would provide us with BioRx's applications,  
8 correspondence relating to such applications, final actions of the Board of Pharmacy, and  
9 enforcement information within the next few days. Upon our request, Ms. Schieldge's colleague,  
10 Erin LaPerle of the California Board of Pharmacy, sent us by facsimile BioRx's most recent  
11 license application in which BioRx identifies its agent for service of process in California  
12 pursuant to the requirements of the Pharmacy Law codified in the California Business and  
13 Professions Code. Attached hereto as Exhibit E is a true and correct copy of this application, in  
14 which BioRx identifies its California agent for service of process as Business Filings, Inc., 1232  
15 Q Street, 1<sup>st</sup> Floor, Sacramento, California.

16

17 I declare under the laws of the State of California that the foregoing is true and correct.

18 Executed this 28th day of July, 2008 in Sacramento, California.

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22

/s/ Aparna Rajagopal-Durbin  
APARNA RAJAGOPAL-DURBIN

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Case No. 2:08-CV-01252-WBS-EFB

**DECLARATION OF APARNA RAJAGOPAL DURBIN IN  
SUPPORT OF OPPOSITION TO DEFENDANT'S MOTION  
TO DISMISS OR TRANSFER**

**EXHIBIT A**



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<p><b>AMBU Inc.</b> 611 N. Hammonds Ferry Road Linthicum, Maryland 21090-1356 Telephone: (800) 262-8462 Fax: (800) 262-8673 Website: <a href="http://www.ambuusa.com">www.ambuusa.com</a></p> <p>AMBU, manufacturer of diagnostic equipment including: ECG Electrodes, EMG needles, EEG Surface Electrodes, Subdermal Needles, Disposable Cup Electrodes, Injection EMG Needles. Contact John Florian, Marketing manager.</p>	<p><b>Applied Neuro Tech Inc.</b> 848 E La Veta Avenue Orange, California 92866 Telephone: (714) 771-4502 Fax: (800) 525-5225 Website: <a href="http://www.appliedneurotech.com">www.appliedneurotech.com</a></p> <p>Applied Neuro Tech (ANT), a California-based equipment manufacturer, is pleased to introduce its new line of cost effective EMG/NCV instruments. Priced at \$9950, the ANT performs EMG, NCV, F-Wave, H-Reflex and Myasthenia. The ANT includes a powerful report writer which can be tailored to your specific needs.</p>
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<p><b>BioRx</b> 5800 Creek Road  Cincinnati, Ohio 45242 Telephone: (866) 44-BIORX</p>	<p><b>Cadwell Laboratories, Inc.</b> 909 N. Kellogg Street Kennewick, Washington 99336 Toll-free: (800) 245-3001 Telephone: (509) 735-6481</p>

Website: [www.biorx.net](http://www.biorx.net)  
**Case 08-cv-01498-JM-BLM Document 42**  
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**Crescent Healthcare, Inc.**

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Telephone: (800) 879-4844  
Fax: (800) 607-5549

Website:

[www.crescenthealthcare.com](http://www.crescenthealthcare.com)

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Website: [www.aanem.org](http://www.aanem.org)

The American Society of Electroneurodiagnostic Technologists, Inc. [ASET] is the largest professional organization representing technologists specializing in the field. ASET offers employment services for employers; innovative educational opportunities through our workshops, distance and online training programs; and actively promotes professional competencies, including our just released competency on Nerve Conduction Studies.

Direct all correspondence pertaining to Support and Exhibits to:

*Jennifer Adler, Exhibit and Foundation Manager*  
[jadler@aanem.org](mailto:jadler@aanem.org)

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**DECLARATION OF APARNA RAJAGOPAL DURBIN IN  
SUPPORT OF OPPOSITION TO DEFENDANT'S MOTION  
TO DISMISS OR TRANSFER**

**EXHIBIT B**



# Patient Resources & News

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## News/Downloads

>> [2008 Neuropathy Action Awareness Day](#)

[California Declares June 26th "Neuropathy Action Awareness Day"](#)

[Davis Enterprise Online Article: "Activists Provide A Voice"](#)

[Neurology Now Article: "Taking Action for Neuropathy"](#)

[LG. Living Article: "Neuropathy Patient Champions Justice for All"](#)

[Media Alert: AZ Hearing on IVIG Access](#)

[Press Release: NAF Urges Congressional Action for IVIG](#)

[Problems Obtaining IVIG?](#)

## 2008 Neuropathy Action Awareness Day

June 26, 2008

The second annual "Neuropathy Action Awareness Day" was held June 26, 2008 at the UCSF Mission Bay Conference Center and was a huge success! The event attracted over 250 attendees, 17 exhibitors, 18 corporate sponsors and top-notch speakers from across the country. The best aspect of this exciting day was that neuropathy patients were not charged one cent for the daytime seminars or the luncheon. The NAF does not feel as though patients should ever have to pay to learn about their disease or to be educated on patient advocacy.

The day was designed to promote public awareness of neuropathy, and to provide helpful information to those who have the disease or who care about someone who does. Several companies, organizations and government entities graciously agreed to exhibit at the event to educate conference attendees about their products and services. The NAF would like to thank the following exhibitors:

- American Red Cross
- Centers for Medicare and Medicaid Services (CMS)
- Crescent Healthcare
- Institute for Restorative Health
- California Department of Insurance
- Coram Specialty Infusion Services
- Office of the California Patient Advocate
- Eli Lilly and Company
- BioRx
- Walgreens - OptionCare
- Northern California Chapter of The Neuropathy Association (NCCNA)
- GBS/CIDP Foundation International
- Origin BioMed Inc. (US)
- Medtronic
- California Department of Managed Healthcare (DMHC)
- Health Insurance Counseling & Advocacy Program (HICAP)
- UCSF Department of Nutrition and Food Services

The daytime seminars consisted of the following topics and speakers:

### **The Spectrum of Neuropathic Analgesia; Approaches to Drug Management, Novel Implantable Devices, and The Legal and Legislative Landscape**

Scott M. Fishman, MD, Chief, Division of Pain Medicine, University of California, Davis

### **There Is Hope—What You Need to Know About Neuropathy: You've Just Come From The Doctor's Office With A Diagnosis, Now What?**

The Northern California Chapter of The Neuropathy Association (NCCNA)

### **IVIG and the Importance of Blood/Plasma**

Patrick Schmidt, CEO, FFF Enterprises & Michelle Vogel, Alliance for Plasma Therapies

### **A New Hope for Diabetic Neuropathy**

**Image Library**  
(Click to Enlarge)



**Alternative Options in Treating Neuropathy**

Ziv M. Peled, MD, Director, Delton Institute for Peripheral Nerve and Plastic Surgery  
Eric I. Hassid, MD & Marco Vespignani, ND, Institute for Restorative Health, Davis, CA

**Neuropathy 101 For Patients**

Jonathan Katz, MD, Chief of Neuromuscular Services, CA Pacific Medical Center  
Jeffrey Ralph, MD, Assistant Clinical Professor, University of CA San Francisco

The buffet luncheon was the highlight of the day for many and featured:

**Richard H. Carmona, M.D., M.P.H., FACS**

17th Surgeon General of the United States (2002 – 2006)  
Vice Chairman, Canyon Ranch  
CEO, Canyon Ranch Health Division  
President, Canyon Ranch Institute

**Trisha Torrey, Every Patient's Advocate**

Ten Tools Smart Patients Use to Navigate Their Medical Care

**"You Are Our Hero Award"**

Recipient - Bev Anderson, President, NCCNA

The day ended with an evening reception, silent auction and dinner. The Master of Ceremonies and award recipient was Carolyn Johnson, ABC, San Francisco. Speakers and entertainment included the following:

**Neuropathy 101 For the General Public**

Todd Levine, MD and David Saperstein, MD  
Banner Good Samaritan Medical Center and Clinical Assistant Professor, University of Arizona

**California Assemblywoman Mary Hayashi (D-Hayward)**

**Special Celebrity Guest Jennifer Holliday**

Grammy and Tony Award-winning American Singer and Actress

The feedback provided on the event was so positive that the NAF is already planning for the 3rd Annual "Neuropathy Action Awareness Day" to be held in June 2009!

110 Pacific Avenue #131 • San Francisco, CA 94111 | (877) 512-7262 | Info@NeuropathyAction.org

Case No. 2:08-CV-01252-WBS-EFB

**DECLARATION OF APARNA RAJAGOPAL DURBIN IN  
SUPPORT OF OPPOSITION TO DEFENDANT'S MOTION  
TO DISMISS OR TRANSFER**

**EXHIBIT C**

Bayer HealthCare  
Pharmaceuticals



Bayer HealthCare  
Pharmaceuticals  
Berkeley, California  
94710 USA  
[www.bayerhealthcare.com](http://www.bayerhealthcare.com)

## News release

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### **Bayer HealthCare and BioRx Introduce Educational Children's Book About Hemophilia**

*The Great Inhibinator is an inspiring story that will be a valuable teaching tool for parents and healthcare providers dealing with inhibitors*

---

**BERKELEY, Calif. & CINCINNATI, Ohio (July 18, 2006)** — Bayer HealthCare Pharmaceuticals and BioRx today announced the availability of *The Great Inhibinator*, a children's book about hemophilia. Written by Chris Perretti Barnes, the mother of a young boy with hemophilia, the book explains inhibitors from the perspective of a young boy recently diagnosed with them. Inhibitors affect a small percentage of people with hemophilia A, and occur when the immune system produces an antibody, or an inhibitor, that prevents the action of replacement factor VIII. The book is a teaching tool for parents and healthcare providers, and provides an easy-to-understand explanation of an inhibitor diagnosis.

Barnes wrote *The Great Inhibinator* to help parents initiate a discussion about how their child feels about living with hemophilia and an inhibitor. The book tells the story of 6-year-old Nate, who is diagnosed with an inhibitor and finds a way to feel empowered despite his diagnosis.

--more--

“For children and teens living with hemophilia A and B, learning and talking about hemophilia and inhibitors can be overwhelming, confusing, and scary,” said author Chris Barnes. “*The Great Inhibinator* can help parents open up lines of communication with their child and begin a discussion in a friendly, fun, and safe way.”

*The Great Inhibinator* chronicles Nate’s quest to find a Halloween costume for trick or treating, and finds an unlikely inspiration for his costume – his inhibitor diagnosis. Nate creates “The Great Inhibinator,” a superhero who fights inhibitors and works to find a cure for hemophilia. He turns a frustrating and overwhelming time for himself and his family into a fun trick or treating event for his whole family.

“Bayer HealthCare is committed to supporting special projects, like *The Great Inhibinator*, to educate young people and their families,” said Terry Tenbrunsel, Vice President of U.S. Sales and Marketing for Kogenate. “*The Great Inhibinator* is a great tool that will help children to better understand inhibitor formation in hemophilia, thereby allowing them to better manage their treatment.”

“We are thrilled to be able to support such an innovative educational tool for the hemophilia community as we strongly believe that education is key to empowering patients and their families,” said Eric Hill, President, BioRx. “We also commend Chris for her initiative, passion and dedication to this community.”

*The Great Inhibinator* is published by BioRx with support from Bayer HealthCare and is now available through both companies. To receive a copy, parents and healthcare providers can call Bayer Customer Service at 888-606-3780, or contact Chris Barnes at 866-44-BIORX (866-442-4679) or [cbarnes@biorx.net](mailto:cbarnes@biorx.net).

Contact:

Sreejit Mohan  
Bayer HealthCare  
Tel.:(510) 705-5477  
E-mail: [sreejit.mohan.b@bayer.com](mailto:sreejit.mohan.b@bayer.com)

Eric Hill  
BioRx  
Tel: 336-688-4909  
E-mail: [ehill@biorx.net](mailto:ehill@biorx.net)

--more--

### **About Hemophilia**

Hemophilia is an inherited bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. About 17,000 Americans have hemophilia. The disease is caused by deficient or defective blood coagulation proteins, known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX.

### **About BioRx**

Based in Cincinnati Ohio, BioRx is a national pharmacy specializing in highly customized care for the bleeding disorders community. As one of the nation's fastest growing providers of hemophilia clotting factors and other specialty pharmaceuticals the company's clinical staff reaches patients and physicians in 43 states. To learn more about BioRx and its products and services visit [www.biorx.net](http://www.biorx.net).

### **About Bayer HealthCare**

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry based in Leverkusen/Germany. In 2005, the Bayer HealthCare subgroup generated sales amounting to some 9.4 billion Euro. Bayer HealthCare employed 33,800 people worldwide in 2005.

The company combines the global activities of the divisions Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Since January 1, 2006 the new Pharmaceutical Division consists of the former Biological Products and Pharmaceutical Division and now comprises three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

### **Forward-looking statements**

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties, and other factors could lead to material differences between the actual future results, financial situation, development, or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

###

# Bayer HealthCare Pharmaceuticals

UNITED STATES

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"For children and teens living with hemophilia A and B, learning and talking about hemophilia and inhibitors can be overwhelming, confusing, and scary," said author Chris Barnes. "The Great Inhibinator can help parents open up lines of communication with their child and begin a discussion in a friendly, fun, and safe way."

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"Bayer HealthCare is committed to supporting special projects, like *The Great Inhibinator*, to educate young people and their families," said Terry Tenbrunsel, Vice President of U.S. Sales and Marketing for Kogenate, Bayer HealthCare Pharmaceuticals. "The Great Inhibinator is a great tool that will help children to better understand inhibitor formation in hemophilia, thereby allowing them to better manage their treatment."

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Case No. 2:08-CV-01252-WBS-EFB

**DECLARATION OF APARNA RAJAGOPAL DURBIN IN  
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TO DISMISS OR TRANSFER**

**EXHIBIT D**



# IGIV THERAPY: THE NURSE'S ROLE IN BALANCING COSTS AND QUALITY OF CARE

A CE monograph based on a symposium at the 2006 INS Annual Meeting\*

## Target Audience: Infusion Nurses

### Faculty

Deanne Birch

Julie Winton, RN, BSN



The University of Nebraska Medical Center College of Nursing Continuing Nursing Education is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity is provided for 1.2 contact hours. Iowa Provider #78. Additionally, provider approved by the California Board of Registered Nursing. Provider #13699 for 1.2 contact hours.

\*This monograph is not sponsored by, nor a part of, the 2006 Infusion Nurses Society Annual Meeting and Industrial Exhibition.



This program is supported by a continuing nursing education grant from Talecris Biotherapeutics, Inc.

## **How to Receive Credit**

Infusion nurses wishing to receive 1.2 contact hours must:

1. Read the monograph (estimated time for completion: 1 hour).
2. Relate the content material to the learning objectives.
3. Answer at least 7 of the 10 self-assessment questions on page 15 correctly.
4. Complete the evaluation form as indicated on page 16.

Upon successful completion of the requirements, a CE certificate will be mailed to you. A certificate will be mailed within 4 to 6 weeks from the date of receipt of your completed evaluation form.

**Release date:** July 30, 2006

**Expiration:** To be eligible to earn (or receive) contact hours, required materials must be postmarked or received no later than July 30, 2007.

## **Disclaimer**

The opinions or views expressed in this continuing education activity are those of the faculty and do not necessarily reflect the opinions or recommendations of the Continuing Education Alliance, the University of Nebraska Medical Center College of Nursing Continuing Nursing Education, or Talecris Biotherapeutics, Inc.

Please contact the Continuing Education Alliance at [inquiries@cealliance.org](mailto:inquiries@cealliance.org) for questions regarding this activity.

# IGIV THERAPY: THE NURSE'S ROLE IN BALANCING COSTS AND QUALITY OF CARE



## Goal

To familiarize infusion nurses with immune globulin products, safety and tolerability considerations, and current issues regarding costs and reimbursement.

## Learning Objectives

After reading the articles in this monograph, participants will be better able to:

- Describe the differences among currently available immune globulin products and their impact on safety, tolerability, and economic considerations.
- Discuss key policies and procedures related to reimbursement for immune globulin therapy in various clinical settings.

## Faculty

### Deanne Birch

Director of Reimbursement  
Managing Member  
Infusion Innovations, LLC  
Salt Lake City, Utah

### Julie Winton, RN, BSN

Director of Business Development–West  
BioRx, LLC  
Baker City, Oregon

## Disclosures



All faculty and planners participating in continuing education activities sponsored by the University of Nebraska Medical Center College of Nursing Continuing Nursing Education are expected to disclose to the audience any significant support or substantial relationship(s) with providers of commercial products and/or devices discussed in this activity and/or with any commercial supporters of the activity. In addition, all faculty are expected to openly disclose any off-label, experimental, or investigational use of drugs or devices discussed in this activity. The faculty and planning committee have been advised that this activity must be free from commercial bias, and based upon all the available scientifically rigorous data from research that conforms to accepted standards of experimental design, data collection, and analysis.

**Ms Birch:** partner: Infusion Innovations, LLC (provider of home infusion pharmacy products).

**Ms Winton:** has no significant relationships to disclose.

The Planning Committee for this activity included Catherine A. Bevil, RN, EdD, of the University of Nebraska Medical Center College of Nursing Continuing Nursing Education, and Craig Borders and Ira Mills of the Continuing Education Alliance. The members of the Planning Committee have no significant relationships to disclose.

# **IGIV THERAPY:**

## **THE NURSE'S ROLE IN BALANCING COSTS AND QUALITY OF CARE**

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Strategies for Optimizing Patient Care With IGIV Therapy.....	2
Current Issues in Cost Management	
and Reimbursement for IGIV Therapy .....	9
Self-Assessment Questions.....	15
Evaluation Form for Nurses.....	16



## Introduction

*Immune globulin therapy is used for antibody replacement and immune system modulation. A wide range of immune globulin products are available. Patients with certain risk factors, however, may be affected by differences in product formulations. In addition, the reimbursement climate continues to change. New policies and procedures have an impact on how immune globulin therapy is coded and what services are covered in various clinical settings.*

*This monograph is based on presentations from a program titled IGIV Therapy: The Nurse's Role in Balancing Costs and Quality of Care, which was held during the Infusion Nurses Society Annual Meeting and Industrial Exhibition in May 2006. In "Strategies for Optimizing Patient Care With IGIV Therapy," Julie Winton, RN, BSN, addresses key strategies for planning optimal administration of immune globulin intravenous (IGIV) or immune globulin subcutaneous (IGSC), managing the infusion process, monitoring patients for adverse effects, and educating patients and their caregivers. In "Current Issues in Cost Management and Reimbursement for IGIV Therapy," Deanne Birch discusses potential cost issues related to IGIV therapy (eg, product manufacturing costs, direct and indirect administration costs, product allocation, and purchasing costs) and the impact of today's reimbursement climate on cost recovery in hospital, physician's office, and home healthcare settings.*

# **IGIV THERAPY: THE NURSE'S ROLE IN BALANCING COSTS AND QUALITY OF CARE**

## **Strategies for Optimizing Patient Care With IGIV Therapy**

**Julie Winton, RN, BSN**  
**Director of Business Development-West**  
**BioRx, LLC**  
**Baker City, Oregon**

Immune globulin products, which consist primarily of immunoglobulin G (IgG), are derived from pooled plasma from healthy blood donors.<sup>1</sup> Currently, the Food and Drug Administration (FDA) has approved IGIV for multiple indications (Table 1). Early in 2006, IGSC received FDA approval for the treatment of primary immune deficiency (PID). However, more than 50% of patients treated with IGIV products receive them for off-label uses.<sup>2</sup>

### **Planning for Optimal Administration Patient Risk Assessment**

A patient risk assessment tool can help clinicians develop a care plan that matches each patient's risk profile with the appropriate immune globulin therapy and thereby minimize infusion reactions (Table 2). At least 70% of the nurses polled during the *IGIV Therapy: The Nurse's Role in Balancing Costs and Quality of Care* program at the 2006 meeting of the Infusion Nurses Society reported that their facility or home healthcare unit does not use a risk-assessment tool to assist in the selection of an immune globulin product. Factors to consider during the risk assessment include the condition for which IGIV or IGSC therapy was prescribed, comorbidities (eg, cardiovascular disease, renal disease, or diabetes mellitus), allergies, history of infusion reactions with immune globulin therapy, and any barriers to intravenous (IV) or subcutaneous (SC) access. The existence of a family or caregiver support system is also

an important consideration, particularly when immune globulin therapy is provided at home.

### **Nurse's Role in Risk Assessment**

From their earliest initiation into nursing school, nurses are trained to carefully assess potential and real problems associated with their patients' diagnoses and therapies. Accordingly, long hours are devoted to care planning. Similarly, this should be viewed as the basis for the nurse's role in risk assessment related to the infusion of IGIV and IGSC. Regardless of the setting (ie, hospital, clinic, or home care), the infusion nurse is responsible for making every effort to minimize the risk to the patient of adverse events during infusion. This in turn minimizes risk for the infusion nurse, the prescriber, the

**Table 1.**

#### **FDA-Approved Indications for IGIV and IGSC**

<b>IGIV</b>	<b>IGSC</b>
Primary immune deficiency (PID)	PID
Idiopathic thrombocytopenic purpura	
Kawasaki syndrome	
Chronic lymphocytic leukemia	
Pediatric HIV infection*	
Bone-marrow transplantation (allogeneic)*	

\*Gammimune N, which is no longer manufactured, was the only IGIV product approved by the FDA for pediatric HIV infection and bone marrow transplantation (allogeneic).

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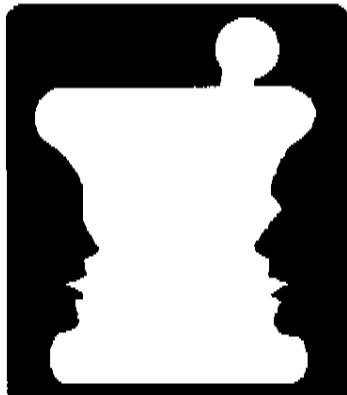
**EXHIBIT E**



**California State Board of Pharmacy**  
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

***BE AWARE & TAKE CARE***  
***Talk to your pharmacist!***



**To:** Michael J Thomas

**Fax:** (916) 444-2100

**From:** Erin LaPerle  
CA Board of Pharmacy

**Pages** 3 **Including cover**

**Phone:** (916) 574-7922

**Date:** 7/28/08

**Re:**

**CC:**

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## NONRESIDENT PHARMACY PERMIT APPLICATION

42281  
60

Please print or type **ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A**

Name of Pharmacy:	Pharmacy Telephone Number		
<b>BioRx</b>	(513) 792-7680		

Address of Pharmacy:	Street and Number	City	State	Zip Code
<b>10828 Kenwood Rd. Cincinnati Ohio 45242</b>				

Indicate whether this application is for:

New Pharmacy       Change of Location of an existing pharmacy       Change of Ownership of an existing pharmacy

If this is a change of ownership or change of location, indicate previous name, address and license number of pharmacy.

<b>5800 Creek Rd. Cincinnati, Ohio 45242</b>	<b>NFP 819</b>
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Date of proposed change of ownership or location:	<b>March 2007</b>
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Please indicate type of ownership:

Individual     Partnership     Corporation     Not-for-profit corporation     Limited Liability

Name of agent for service of process in California	Agent's telephone number
<b>Business Filings, Inc.</b>	(800) 981-7183

Agent's California address (P.O. box not acceptable)	City	State	Zip Code
<b>1232 Q Street, 15th Floor</b>	<b>Sacramento, CA 95814</b>		

Toll-Free Telephone Number for patient-pharmacist communication <b>1-888 866 - 442 - 4679</b>	Resident State pharmacy permit # & date issued <b>Ohio # 02-1444900 Issued 6/04</b>
--	--

Do you mail replacement contact lenses to patients in California? Yes  No

By your affirmative answer above, your pharmacy name will be provided to the California Medical Board and you will be in compliance with section 4124 of the California Business and Professions Code.

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<input type="checkbox"/> Partner agreement	<input type="checkbox"/> Stock Cert	Denied _____	Date _____
<input type="checkbox"/> Seller's certificate	<input type="checkbox"/> By Laws	Date <b>1/22/08</b>	Amount of fee _____
<input type="checkbox"/> Whse agreement	<input checked="" type="checkbox"/> Lease		

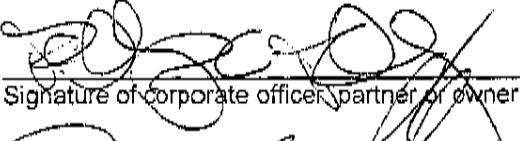
Name of pharmacist-in-charge <i>Mark R. Kestles</i>	Pharmacist license number 03-2-15192
Residence address [REDACTED]	City [REDACTED] State [REDACTED] Zip code [REDACTED]
Indicate if you want all correspondence mailed to a different address. If correspondence should be mailed to the pharmacy, please insert "Same as Pharmacy." <i>SAME AS PHARMACY</i>	
Name and telephone number of contact person to clarify information provided on this application. <i>Mark Kestles</i>	e-mail address: [REDACTED]

**PLEASE READ CAREFULLY**

This application must be approved by the California State Board of Pharmacy before a pharmacy permit will be issued. If changes are made during the application process, you may need to submit a new application with the appropriate fees. Any application not completed within 60 days of receipt may be deemed withdrawn by the Board of Pharmacy. Fees applied to this application are not transferable and are not refundable.

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 574-7900, 1625 N. Market Blvd, Suite N219, Sacramento, California 95834. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the owner or an executive officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant's or applicants' business to be conducted under the license(s) for which this application is made; (4) all supplemental statements are true and accurate; and (5) the transfer application may be withdrawn by either the applicant or the licensee with no resulting liability to the Board of Pharmacy.

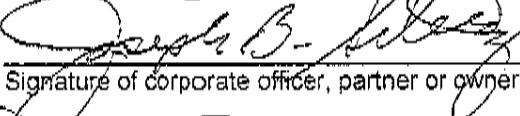
  
Signature of corporate officer, partner or owner

Philip C. Rieley

Name (please print)

President

Title

  
Signature of corporate officer, partner or owner

Joseph B. Subring

Name (please print)

Member

Title

  
Signature of corporate officer, partner or owner

Douglas Eric Hill

Name (please print)

VP / Member

Title

Date \_\_\_\_\_